

REMARKS/ARGUMENTS

Status of the Claims

Upon entry of this amendment, claims 83 and 84 will remain pending in the application and claims 1-82 and 85-107 will be canceled without prejudice or disclaimer. Claims 83 and 84 are proposed to be amended as set forth above. The claims have been amended to recite that the composition "consists of" cetylpyridinium chloride, propylene glycol and water in the recited amounts as suggested by the Examiner in the Advisory Action. As the amendment after final filed on February 2, 2004 was not entered by the Examiner, the claims have been amended accordingly.

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow. The amendments to claims 83 and 84 are made to address the Examiner's comments in the Advisory Action. Entry of this amendment is kindly requested because none of the amendments raise new issues or contain new matter and the amendments reduce issues for appeal. The amendment of claims 83 and 84 should not be construed as the surrender of any subject matter, and Applicants reserve the right to file one or more continuing applications on any canceled subject matter. The amended claims have support in the original claims and specification as filed.

Telephonic Interview

The undersigned's colleague, Ms. Till, appreciates the courtesies extended to her during the telephonic interview of January 15, 2004. The Examiner and Ms. Till discussed the Declaration submitted under 37 C.F.R. § 1.132 which was filed with the response of May 27, 2003 and its impact on claims 85 and 90 which recite that the quaternary ammonium compound is cetylpyridinium chloride. The Examiner stated that he would reconsider the Declaration of Dr. Kelly W. Beers in light of the amendments to the claims.

Further Telephonic Interview

The undersigned and the Examiner discussed amendments to the claims in light of the Advisory Action mailed February 26, 2004 on March 2, 2004.

Claim Rejections - 35 U.S.C. § 102

The rejection of claims 52, 82-84, 86-87, 102-103 and 107 under 35 U.S.C. § 102 (e) as being anticipated by Smith et al. (U.S. Patent No. 5,414,124) has been maintained by the PTO. Applicants respectfully traverse the rejection.

To reiterate Applicants' position, in order for a reference to anticipate the claimed invention, the cited reference must disclose each and every limitation of the claimed invention. The Examiner asserts that the weight basis of the compositions is undesignated and has calculated percentages of quaternary ammonium compound (QAC) in the compositions disclosed in Table II of Smith. It is respectfully submitted that the Examiner has misinterpreted the information in Table II of Smith. The Examiner provides two examples of calculations which he concludes are solutions with 33% and 40% QAC, respectively. The Examiner uses in his first calculation the example of a 50/50 mixture of benzalkonium chloride or bromide and didecyldimethylammonium chloride or bromide. Here, the Examiner appears to have neglected to include in the calculation that the 50/50 mixture of a 80% solution having 52% water and 48% propylene glycol has not only benzalkonium chloride but also, didecyldimethylammonium chloride. The same is true for the calculation for the 50/50 mixture of a 50% solution having 16% water and 84% propylene glycol. Furthermore, col. 3, lines 23-34 of Smith clearly teach that the amount of quaternary ammonium compound present in each of the solutions of Table II is 50% or 80%. This disclosure enforces the earlier discussion of Smith's invention, where the solution is described as having "about 50% to about 80% of a quaternary ammonium compound." Applicants have calculated the percent of QAC in each of examples 1-12 of Smith and have determined the percent of QAC. A table showing the % QAC as calculated from Examples 1-12 is attached hereto as Exhibit 1. Based on the miscalculation and the failure of Smith to disclose cetyl pyridinium chloride as a QAC useful in his invention, Smith cannot anticipate the present claims. Because Smith et al. fails to disclose each and every limitation of the claimed invention, the claimed invention is not anticipated by Smith et al.

Furthermore, in light of Applicants' claim amendments to a composition consisting of cetylpyridinium chloride present at a concentration of about 40% by weight and propylene

glycol present at a concentration ranging from about 55% by weight to about 60% by weight, and wherein said solution further comprises water up to about 5% by weight, the rejection of claims 52, 82-84, 86-87, 102-103 and 107 is moot. However, it is noted that the claims have been so limited only for purposes of expediting prosecution toward allowance and Applicants reserve the right to file one or more continuation application directed to claims previously presented herein.

Applicants respectfully request reconsideration and withdrawal of the rejection.

Claim Rejections - 35 U.S.C. § 103

A. Rejection Of Claims 53-61, 65-81, 85 And 90-101
Under 35 U.S.C. § 103 As Being Unpatentable Over Smith Et
Al. In View Of Gauvreau

The rejection of claims 53-61, 65-81, 85 and 90-101 is maintained by the Examiner under 35 U.S.C. § 103 as being obvious over Smith et al. in view of Gauvreau. The Examiner maintains the rejection and only elaborates to states that Smith/Gauvreau disclose known charged quaternary ammonium compounds with a long history of germicidal activity. Applicants respectfully disagree with the Examiner, especially in light of the Declaration under 37 C.F.R. 1.132 of Dr. Kelly Beers submitted May 27, 2003 and amendments to the claims.

Applicants maintain that the amended claims are not obvious over the combined disclosures of Smith et al. and Gauvreau because the combined disclosures of Smith et al. and Gauvreau do not teach each and every limitation of the claims. As discussed above, Smith et al. teaches a composition comprising about 50-80% of a quaternary ammonium compound. Smith does not teach a composition comprising greater than about 15% by weight to about 40% by weight of cetylpyridinium chloride, as recited in claims 52 (upon which claims 59, 62, 63, 64, 77, 79, 80, 81, 86, 87, 88, and 89 depend) and 76. Smith does not teach a composition comprising greater than about 10% of cetylpyridinium chloride, as recited in claim 55 (upon which claims 58, 60, 65, 67, 69, 71, 74, 76 and 78 depend). Smith does not teach a composition comprising greater than about 40% of cetylpyridinium chloride, as recited in claim 82 (upon which claims 83 and 84 depend). Smith does not teach a

composition comprising greater than about 10% of cetylpyridinium chloride, as recited in claim 91 wherein the composition does not contain a flavoring oil. Smith does not teach a composition comprising cetylpyridinium chloride with a concentration of up to about 1% by weight, as recited in claim 94 (upon which claims 97-101 depend), wherein the composition does not contain one or more flavoring oils. In fact, Smith et al. does not teach cetylpyridinium chloride at all. Gauvreau does not cure the deficiencies of Smith et al which do not teach the claimed concentration ranges, and therefore, the claims are not obvious over Smith et al. in view of Gauvreau.

Moreover, the Examiner has failed to establish a *prima facie* case of obviousness. A proper rejection for obviousness under §103 requires consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition, or device, or carry out the claimed process and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success. Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the applicant's disclosure. [emphasis added] *In re Vaeck*, 947 F.2d 488, 493, 20 USPQ2d 1438 (Fed. Cir. 1991).

As previously discussed in the response dated May 27, 2003, neither Smith et al. nor Gauvreau would have suggested to a person of ordinary skill in the art to either include cetyl pyridinium in the composition of Smith et al. for an additive disinfecting effect or to substitute cetyl pyridinium for the quaternary ammonium compounds of Smith et al.

Applicants response of May 27, 2003 stated:

As stated in Gauvreau. column 2, lines 35-43, the composition of Gauvreau comprises the following two active constituents: (a) a halide salt of a pyridinium compound and (b) a member of the group of organic compounds all having ten carbon atoms consisting of the terpenes and their oxygenated derivatives. Gauvreau discloses the synergistic effects that are achieved when these two active constituents are combined in one composition. For example, column 6, lines 23-28 of Gauvreau state "the admixture of the two ingredients produces an improvement in antimicrobial activity which in some cases is more than a thousand times

that of either constituent alone. This clearly demonstrates that a strong synergistic potentiation is achieved.” Gauvreau provides data showing the improvements of antimicrobial activity for a combination of cetyl pyridinium halide salts with various monoterpenes as compared to the separate antimicrobial activity for each compound. *See* Tables III and IV of Gauvreau. The synergistic effects disclosed by Gauvreau for the combination of a cetyl pyridinium halide salt and a terpene would have motivated a person of ordinary skill in the art to make antimicrobial compositions comprising both cetyl pyridinium and a terpene. However, a person of ordinary skill in the art would not have been motivated to make an antimicrobial composition containing cetyl pyridinium yet not containing a terpene. Therefore, it would not have been obvious to a person of ordinary skill in the art to either include cetyl pyridinium in the composition of Smith et al. for an additive disinfecting effect or to substitute cetyl pyridinium for the quaternary ammonium compound of Smith et al. because the compounds of Smith et al. do not contain a terpene.

Furthermore, as discussed previously, Gauvreau’s invention lies in the synergistic effects of a composition comprising two active constituents, a halide salt of a pyridinium compound and a terpene. Because the composition of Smith et al. does not contain a terpene, a person of ordinary skill in the art would not have had a reasonable expectation of success in including cetyl pyridinium in the composition of Smith et al. or substituting cetyl pyridinium for the quaternary ammonium compound of Smith et al. As discussed above, Gauvreau discloses the synergistic effects of a composition comprising two active constituents, a halide salt of a pyridinium compound and a terpene.

Therefore, the combination of Smith and Gauvreau fails to teach or suggest the recited compositions of claims 53-61, 65-81, 85 and 90-101.

Furthermore, in light of Applicants’ claim amendments to a composition consisting of cetylpyridinium chloride present at a concentration of about 40% by weight and propylene glycol present at a concentration ranging from about 55% by weight to about 60% by weight, and wherein said solution further comprises water up to about 5% by weight, the rejection of claims 53-61, 65-81, 85 and 90-101 is moot. However, it is noted that the claims have been so amended only for purposes of expediting prosecution toward allowance and Applicants

reserve the right to file one or more continuation application directed to claims previously presented herein.

Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

B. Rejection Of Claims 62, 89 and 104-106 Under 35 U.S.C. § 103 As Being Unpatentable Over Smith Et Al. In View Of The Merck Index

The rejection of claims 62, 89 and 104-106 is maintained by the Examiner under 35 U.S.C. § 103 as being obvious over Smith et al. in view if the Merck Index. Applicants respectfully traverse the rejection.

The Examiner maintains the rejection but does not elaborate on the basis for the rejection.

Applicants maintain that claims 62, 89 and 104-106 are not obvious over the combined disclosures of Smith et al. and the Merck Index because the combined disclosures of Smith et al. and the Merck Index do not teach each and every limitation of the claims. As discussed above, Smith et al. teaches a composition comprising about 50-80% of an quaternary ammonium compound. Smith does not teach a composition comprising greater than about 15% by weight to about 40% by weight of cetylpyridinium chloride, as recited in claim 52, upon which claims 62 and 89 depend. Additionally, Smith et al. does not teach a composition consisting essentially of cetylpyridinium chloride with a concentration of up to about 1% by weight, as claimed in claim 102, upon which claims 104-106 depend. The Merck Index does not cure the deficiencies of Smith et al. Because the combined disclosures of Smith et al. and the Merck Index do not teach each and every limitation of claims 62, 89 and 104-106, the claimed invention is not obvious over Smith et al. in view of the Merck Index.

Applicants disagree with the Examiner's rejection of claims 62, 89 and 104-106 as being obvious over Smith et al. in view of the Merck Index for the reasons discussed above and in light of the amended claims. However, assuming, *arguendo*, that the combined

disclosures of Smith et al. and the Merck Index did disclose each and every limitation of the claimed invention, the present invention is not obvious over Smith et al. in view of the Merck Index because, in contrast to the Examiner's assertion that propylene glycol and glycerol are substitutes for each other, the solubility, foam dispersion and miscibility of the quaternary ammonium compound of the present invention in propylene glycol are superior as compared to the same properties in glycerol. The choice of propylene glycol was discussed at length in the previously filed response of May 27, 2003 with the accompanying Declaration under 37 C.F.R. § 1.132 of Dr. Kelly W. Beers. As previously stated, Dr. Kelly W. Beers provided in the 132 Declaration (submitted with response of May 27, 2003), a comparison of the solubility, foam dispersion and miscibility of cetylpyridinium chloride (CPC) in propylene glycol (PG), to the same properties for a composition of CPC in ethanol and glycerol. It is respectfully requested that the Examiner reconsider the evidence submitted in the Declaration under 37 C.F.R. § 1.132 by Dr. Kelly W. Beers in light of the present claims which recite that the QAC is cetylpyridinium chloride.

Furthermore, in light of Applicants' claim amendments to a composition consisting of cetylpyridinium chloride present at a concentration of about 40% by weight and propylene glycol present at a concentration ranging from about 55% by weight to about 60% by weight, and wherein said solution further comprises water up to about 5% by weight, the rejection of claims 62, 89 and 104-106 is moot. However, it is noted that the claims have been so limited only for purposes of expediting prosecution toward allowance and Applicants reserve the right to file one or more continuation application directed to claims previously presented herein.

Based upon all of these arguments, withdrawal of this rejection is respectfully requested.

C. Rejection Of Claim 88 Under 35 U.S.C. § 103 As Being Unpatentable Over Hall In View Of Vidra and Further In View of The Merck Index

The rejection of claim 88 is maintained by the Examiner under 35 U.S.C. § 103 as being obvious over Hall in view of Vidra and the Merck Index. The Examiner maintains the

rejection of claim 88 over Hall in view of Vidra and the Merck Index without elaborating on the basis of the rejection. It is respectfully submitted that Hall does not teach a composition comprising greater than about 15% by weight to about 40% by weight of a cetylpyridinium chloride, as recited in claim 52 from which claim 88 depends. Applicants do not agree with the Examiner's rejection that Vidra and the Merck Index cure the deficiencies of Hall et al.

Applicants maintain their disagreement with the Examiner's rejection of claim 88 as being obvious over Hall in view of Vidra and further in view of the Merck Index for the reasons discussed above. However, assuming, *arguendo*, that the combined disclosures of Hall, Vidra and the Merck Index did disclose each and every limitation of the claimed invention, the present invention is not obvious over Hall in view of Vidra and further in view of the Merck Index because, for the reasons discussed above and in the previous response of May 27, 2003, the solubility, foam dispersion and miscibility of cetylpyridinium chloride in the composition of the present invention in propylene glycol are superior as compared to the same properties in ethanol as shown in the Declaration of Dr. Kelly W. Beers submitted with the response of May 27, 2003.

Furthermore, in light of Applicants' claim amendments to a composition consisting of cetylpyridinium chloride present at a concentration of about 40% by weight and propylene glycol present at a concentration ranging from about 55% by weight to about 60% by weight, and wherein said solution further comprises water up to about 5% by weight, the rejection of claim 88 is moot. However, it is noted that the claims have been so amended only for purposes of expediting prosecution toward allowance and Applicants reserve the right to file one or more continuation application directed to claims previously presented herein.

Based upon the above arguments and the amendments to the claims, it is requested that this rejection be withdrawn.

CONCLUSION

Applicants submit that the present application is now in condition for allowance. Entry of the present amendment is respectfully requested. Favorable reconsideration of the application as amended is respectfully requested.

If the Examiner has any questions concerning this application, he is requested to contact the undersigned.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date March 12, 2004

By Jayme A. Huleatt

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5542
Facsimile: (202) 672-5399

Jayme A. Huleatt
Attorney for Applicant
Registration No. 34,485